

Appendix D

**Applicants' Previous Response to
the PTO's Administrative Requirement Filed December 29, 1998**

Claim 17 stands rejected under 35 U.S.C. § 103 (a) as being unpatentable over Campbell, U.S. Pat. No. 4,536,791, in view of Lambert, U.S. Pat No. 4,381,522, and further in view of Nagel, U.S. Pat. No. 4,536,791.

Claims 2-20 remain active in this application. No new matter is presented in the foregoing amendments. Approval and entry of same is respectfully requested.

B. Response to Requirement Imposed Upon Applicants to Resolve Alleged Conflicts Between Applicants' Applications.

Applicants note that the requirement of paragraph 8 of the Final Office Action mailed January 8, 1998, has been essentially reiterated in paragraph 4 of the recent Office Action. Applicants respectfully maintain the traversal of the requirements of paragraph 4 of the Office Action and reiterate below the reasons for traversal.

Paragraph 4 of the Office Action requires Applicants to either:

- (1) file terminal disclaimers in each of the related 328 applications terminally disclaiming each of the other 327 applications; or
- (2) provide an affidavit attesting to the fact that all claims in the 328 applications have been reviewed by applicant and that no conflicting claims exist between the applications; or
- (3) resolve all conflicts between claims in the related 328 applications by identifying how all the claims in the instant application are distinct and separate inventions from all the claims in the above identified 328 applications.

In addition, Examiner states that failure to comply with any one of these requirements will result in abandonment of the application.

Examiner states that the requirement has been made because conflicts exist between claims of the related co-pending applications, including the present application. Examiner sets forth only the serial numbers of the co-pending applications without an indication of which claims are conflicting. Examiner has also attached an Appendix providing what is deemed to be clear evidence that conflicting claims exist between the 328 related co-pending applications and the present application. Further, Examiner states that an analysis of all claims in the 328 related

co-pending applications would be an extreme burden on the Office requiring millions of claim comparisons.

Applicants respectfully traverse these requirements in that Examiner has both improperly imposed the requirements, and has incorrectly indicated that abandonment will occur upon failure to comply with the requirement. Applicants' traversal is supported by the fact that 37 C.F.R. § 1.78 (b) does not, under the present circumstances, provide Examiner with authority to require Applicants to either: 1) file terminal disclaimers; 2) file an affidavit; or 3) resolve all apparent conflicts. Additionally, the penalty of abandonment of the instant application for failure to comply with the aforementioned requirement is improper for being outside the legitimate authority to impose abandonment upon an application. The following remarks in Section (B) will explain Applicants' basis for this traversal.

**1. The PTO's New Requirement is an Unlawfully
Promulgated Substantive Rule Outside the
Commissioner's Statutory Grant of Power**

The PTO Commissioner obtains his statutory rulemaking authority from the Congress through the provisions of Title 35 of the United States Code. The broadest grant of rulemaking authority -- 35 U.S.C. § 6 (a) -- permits the Commissioner to promulgate regulations directed only to "the conduct of proceedings in the [PTO]". This provision does NOT grant the Commissioner authority to issue substantive rules of patent law. Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 930, 18 U.S.P.Q.2d 1677, 1686 (Fed Cir. 1991).¹ Applicants respectfully submit that the Examiner's creation of a new set of requirements based upon 37 CFR § 1.78(b) constitutes an unlawful promulgation of a substantive rule in direct contradiction of a long-established statutory and regulatory scheme.

¹ Accord Hoechst Aktiengesellschaft v. Quigg, 917 F.2d 522, 526, 16 U.S.P.Q.2d 1549, 1552 (Fed Cir. 1990); Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 398-99, 13 U.S.P.Q.2d 1628, 1632-33 (Fed. Cir. 1990); Ethicon Inc. v. Quigg, 849 F.2d 1422, 1425, 7 U.S.P.Q.2d 1152, 1154 (Fed. Cir 1988).

2. The PTO's Requirement is a Substantive Rule

The first determination is whether the requirement as imposed by the PTO upon Applicants is substantive or a procedural rule. The Administrative Procedure Act offers general guidelines under which all administrative agencies must operate. A fundamental premise of administrative law is that administrative agencies must act solely within their statutory grant of power. *Chevron v. Natural Resources Defense Council*, 467 U.S. 837 (1984). The PTO Commissioner has NOT been granted power to promulgate substantive rules of patent law. *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996), citing, *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 930, 18 U.S.P.Q.2d 1677, 1686 (Fed. Cir. 1991).

The appropriate test for such a determination is an assessment of the rule's impact on the Applicant's rights and interests under the patent laws. *Fressola v. Manbeck*, 36 U.S.P.Q.2d 1211, 1215 (D.D.C. 1995). As the PTO Commissioner has no power to promulgate substantive rules, the Commissioner receives no deference in his interpretation of the statutes and laws that give rise to the instant requirement. *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543 (Fed Cir. 1996), citing, *Chevron v. Natural Resources Defense Council*, 467 U.S. 837 (1984). When agency rules either (a) depart from existing practice or (b) impact the substantive rights and interests of the effected party, the rule must be considered substantive. *Nat'l Ass'n of Home Health Agencies v. Scheiker*, 690 F.2d 932, 949 (D.C. Cir. 1982), *cert. denied*, 459 U.S. 1205 (1983).

a. The PTO Requirement is Substantive Because it Radically Changes Long Existing Patent Practice by Creating a New Requirement Upon Applicants Outside the Scope of 37 C.F.R. § 1.78 (b)

The Examiner's requirement is totally distinguishable from the well articulated requirement authorized by 37 CFR § 1.78 (b), because it (1) creates and imposes a new requirement to avoid abandonment of the application based on the allegation that conflicts exist between claims of the related 328 co-pending applications, and (2) it results in an effective final double patenting rejection without the PTO's affirmative double patenting rejection of the

claims. Long existing patent practice recognizes only two types of double patenting, double patenting based on 35 U.S.C. § 101 (statutory double patenting) and double patenting analogous to 35 U.S.C. § 103 (the well-known obviousness type double patenting).² These two well established types of double patenting use an objective standard to determine when they are appropriate³ and have a determinable result on the allowability of the pending claims.

The Examiner's new requirement represents a radical departure from long existing patent practice relevant to conflicting claims between co-pending applications of the same inventive entity. Two well established double patenting standards are based on an objective analysis of comparing pending and *allowed* claims. However, in the present application, there are no *allowed* claims. The Examiner's new requirement to avoid a double patenting rejection presumes that conflicts exist between claims in the present application and claims in the 327 copending applications. This presumption of conflicts between claims represents a radical departure from long existing patent practice as defined by 37 C.F.R. § 1.78 (b), which states:

Where two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.

Clearly, the only requirement authorized by the rule is the elimination of conflicting claims from all but one application where claims have been determined to exist. Furthermore, in order to determine that conflicting claims do in fact exist in multiple applications, the only possible analysis is obviousness-type double patenting, since there are no allowed or issued

²MPEP § 804(B)(1) states, in an admittedly awkward fashion, that the inquiry for obviousness type double patenting is analogous to a rejection under 35 U.S.C. 103: "since the analysis employed in an obvious-type double patenting determination parallels the guidelines for a 35 U.S.C. 103 rejection, the factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 U.S.P.Q. 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis".

³ The objective test for same invention double patenting is whether one of the claims being compared could be literally infringed without literally infringing the other. The objective test for obviousness type double patenting is the same as the objective nonobviousness requirement of patentability with the difference that the disclosure of the first patent may not be used as prior art.

claims by which to employ the 35 U.S.C. § 101 statutory double patenting analysis. Once obviousness-type double patenting analysis has been applied and conflicting claims have been determined to exist, only a *provisional* obviousness-type double patenting rejection is possible until claims from one application are allowed.

In summary, the Examiner's new requirement departs from long-established practice because it (1) creates and imposes a new requirement to avoid abandonment of the application based on the allegation that conflicts exist between claims of the related 328 co-pending applications, and (2) it results in an effective final double patenting rejection without the PTO's affirmative double patenting rejection of the claims.

Therefore, the Examiner's new requirement departs from existing practice and therefore is a substantive rule beyond the authority of the PTO and is therefore, invalid.

**b. The New Requirement is Also a Substantive Rule
Because it Adversely Impacts the Rights and
Interests of Applicants to Benefits of the Patent**

The rights and benefits of a U.S. patent is solely a statutory right. *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543 (Fed Cir. 1996). The essential statutory right in a patent is the right to exclude others from making, using and selling the claimed invention during the term of the patent. Courts have recognized that sometimes new procedural rules of the PTO are actually substantive rules, e.g. when the new rule made a substantive difference in the ability of the applicant to claim his discovery. *Freesola v. Manbeck*, 36 U.S.P.Q.2d 1211, 1214 (D.D.C. 1995) (emphasis added), citing, *In re Pilkington*, 411 F.2d 1345, 1349; 162 U.S.P.Q. 145 (C.C.P.A. 1969); and *In re Steppan*, 394 F.2d 1013, 1019; 156 U.S.P.Q. 143 (C.C.P.A. 1967).

The new requirement, on its face and as applied here, is an instance of a PTO rule making a substantive difference in Applicants ability to claim their invention and, therefore, must be considered a substantive rule. The requirement denies Applicants rights and benefits expressly conferred by the patent statute. The measure of the value of these denied rights and benefits is that the requirement, as applied here, would deny Applicants the full and complete PTO

examination of Applicants' claims on their merits, as specified by 37 C.F.R. § 1.105. In addition, to file terminal disclaimers in each of the related 328 applications terminally disclaiming each of the other 327 applications based on the PTO's incomplete examination on the merits would deny Applicants' the benefit of the full patent term of 17 years on each of Applicants' respective applications. Applicants respectfully submit that the requirement has a huge impact on their rights and interests in the presently claimed invention.

c. Conclusion: Substantive Rule

In summary, the requirement is a change to long existing practice and/or has a substantive impact on the rights and interests of Applicants to their invention. Either finding means that the new requirement is a substantive rule. Since the Commissioner has no power to issue substantive rules, the requirement is an improperly promulgated substantive rule having no force of law.

3. The PTO Requirement is Outside the Scope of 37 C.F.R. § 1.78 (b)

Rule 78 (b) states that:

Where two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.

The only **requirement** that Rule 78 (b) authorizes is the elimination of conflicting claims from all but one co-pending applications.

In the instant Office Action, Examiner has not required the elimination of all conflicting claims from all but one application, but instead has required Applicants to: 1) file terminal disclaimers in each of the related 328 applications; 2) provide an affidavit; or 3) resolve all conflicts between claims in the related 328 applications. None of the options in the requirement is authorize by Rule 78 (b), and therefore Applicants respectfully submit that such a requirement is improper.

With respect to the PTO's authority to act within Rule 78 (b) regarding the rejection of conflicting claims, M.P.E.P § 822.01 states that:

Under 37 CFR § 1.78 (b), the practice relative to overlapping claims in applications copending before the examiner..., is as follows: Where claims in one application are unpatentable over claims of another application of the same inventive entity because they recite the same invention, *a complete examination should be made of the claims of each application* and all appropriate rejections should be entered in each application, including rejections based upon prior art. *The claims of each application may also be rejected on the grounds of provisional double patenting on the claims of the other application* whether or not any claims avoid the prior art. Where appropriate, the same prior art may be relied upon in each of the applications. MPEP 822.01 (6th Ed., Rev. 3, 1997), (*emphasis added*).

In light of the requirement of the Office Action, M.P.E.P § 822.01 and 37 CFR § 1.78 (b) are not applicable since there has not been any rejection with regard to the elimination of conflicting claims from all but one co-pending application.

4. The Assertion That Failure to Comply with the Requirement Will Result in Abandonment of Applicants' Application is Improper

Applicants' prospective failure to comply with the above requirements cannot properly result in abandonment of the present application. Applicants respectfully submit that abandonment of an application can properly occur only:

- (1) for failure to respond within a provided time period (under Rule 135);
- (2) as an express abandonment (under Rule 138); or
- (3) the result of failing to timely pay the issue fee (under Rule 316).

There is no provision in the rules permitting abandonment for failure to comply with any of the presented requirements. To impose an improper requirement upon Applicants and then hold the application is to be abandoned for failure to comply with the improper requirement violates the rules of practice before the USPTO. Furthermore, Examiner is in effect attempting to create a substantive rule which is above and beyond the rulemaking authority of the USPTO, and therefore is invalid.

In the *Application of Mott*, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976), the applicant had conflicting claims in multiple applications. The CCPA held that action by Examiner which would result in automatic abandonment of the application was legally untenable. *Id.* at 1296, 190 USPQ at 541. In the present application, Examiner has asserted that there are conflicting claims in multiple applications, and that non-compliance of the Office Action's requirement will result in an automatic abandonment. Therefore, under *Mott's* analysis, the Office Action's result of abandonment of Applicant's application is legally untenable.

5. Response to Apparent Conflict of Claims

Applicants submit that the presentation of the Office Action Appendix fails to demonstrate any conflicts between claims of the present application and claims of the co-pending applications. Rather, the Office Action Appendix compares representative claims of *other* applications in attempt to establish that "conflicting claims exist between the 328 related co-pending applications." Absent any evidence of conflicting claims between the Applicants' present application and any other of Applicants' co-pending applications, any requirement imposed upon Applicants to resolve such alleged conflicts is improper.

6. Request for Withdrawal of Requirement

Therefore, Applicants respectfully request that Examiner reconsider and withdraw the requirement that Applicants: (1) file terminal disclaimers in each of the related 328 applications terminally disclaiming each of the other 327 applications; (2) provide an affidavit attesting to the fact that all claims in the 328 applications have been reviewed by applicant and that no conflicting claims exist between the applications; or (3) resolve all conflicts between claims in the above identified 328 applications by identifying how all the claims in the instant application are distinct and separate inventions from all the claims in the above identified 328 applications, which upon failing to do so will abandon the application.

7. Filing of Supplemental Oath

Notwithstanding the foregoing, Applicants will file a supplemental oath under 37 C.F.R. § 1.67 for each application when Examiner identifies allowable subject matter. Applicants respectfully propose that the filing of individual supplemental oaths attesting to the absence of claim conflicts between previously patented claims and subsequently allowed claims is a more reasonable method of ensuring the patentable distinctness of subsequently allowed claims.

Under 37 C.F.R. § 1.105, § 1.106 & § 1.78 (b), Examiner has the duty to make every applicable rejection, including double patenting rejection. Failure to make every proper rejection denies Applicants all rights and benefits related thereto, e.g., Applicants' right to appeal, etc. Once obviousness-type double patenting analysis has been applied and conflicting claims have been determined to exist, only a *provisional* obviousness-type double patenting rejection is possible until claims from one application are allowed.

C. Response to Rejections under 35 U.S.C. § 112

1. Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 2-8 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. It is noted that the phrase "said at least two or more specific portions" in claim 2 lacked sufficient antecedent basis. Claim 2 has been amended to positively set forth "at least two or more specific portions."

2. Conclusion

Applicants respectfully submit that claims 2-8 particularly point out and claim the subject matter sufficiently for one of ordinary skill in the art to comprehend the bounds of the claimed invention. The test for definiteness of a claim is whether one skilled in the art would understand the bounds of the patent claim when read in light of the specification, and if the claims so read reasonably apprise those skilled in the art of the scope of the invention, no more is required. *Credle v. Bond*, 25 F.3d 1556, 30 U.S.P.Q.2d 1911 (Fed. Cir. 1994). The legal standard for